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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,881	03/15/2002	Howard Kaufman	MDS-030	5399
51414	7590	11/28/2005	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			MISTRY, O NEAL RAJAN	
			ART UNIT	PAPER NUMBER
			2625	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,881 ✓

Applicant(s)

KAUFMAN ET AL.

Examiner

O'Neal R. Mistry

Art Unit

2625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 March 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. The response received on 09/06/2005 has been placed in the file and was considered by the examiner. An action on the merits follows.

Response to Arguments

2. The arguments filed on 09/06/2005 have been fully considered. A response to these arguments is provided below.

Examiner's Response:

3. Applicant's arguments with respect to claim 40-70 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 40,42-44,46-56,59-60,62-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman (USPN 6,671,540) and Balas (US Publication 2002/0007123).

In regards to claim 40, Balas discloses steps a) applying a chemical agent to a tissue (paragraph 20), step b) obtaining a temporal sequence of images of the tissue following application of the chemical agent to the tissue (paragraph 20).

Balas does not expressly disclose step c) determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent, step d) repeating step (c), thereby differentiating regions according to how tissue in each region responds to the chemical agent; and step e) locating a portion of the tissue with a characteristic of interest, the located portion corresponding to at least one of the differentiated regions.

However, Hochman discloses step c) determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent (col. 6 lines 5-20), step d) repeating step (c), thereby differentiating regions according to how tissue in each region responds to the chemical agent (col. 6 lines 20-30); and step e) locating a portion of the tissue with a characteristic of interest, the located portion corresponding to at least one of the differentiated regions (col. 5 lines 40-65, col. 7 line 39-50).

Balas & Hochman are combinable because they are from the same field of endeavor i.e. biomedical imaging (paragraph 2, Balas) & (col. 1 line 20-34, Hochman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Hochman into the system of Balas.

The suggestion/motivation for doing so would have been to one of ordinary skill in the art to combine because it allows a method of improving detections of tumors quickly for patients by reducing the amount of the time the patients spends the in hospital (col. 2), as taught by Hochman.

Therefore, it would have been obvious to combine Balas with Hochman to obtain the invention as specified in claim 40.

In regards to claim 43, Balas in view of Hochman discloses step (d) comprises repeating step (c) for each of a plurality of pairs of selected regions (col. 7 lines 39-50, Hochman).

In regards to claim 44, Balas in view of Hochman discloses the measure of similarity indicates a similarity in evolution of mean intensity of each region following application of the chemical agent (col. 2 lines 62- col. 3 line 10).

In regards to claim 46, Balas in view of Hochman discloses a member selected from the group consisting of acetic acid, formic acid, propionic acid, butyric acid, Lugol's iodine, Shiller's iodine, methylene blue, toluidine blue, and indigo carmine (para. 21)

In regards to claim 47, Balas in view of Hochman discloses the chemical agent comprises acetic acid (para. 21).

In regards to claim 48, Balas in view of Hochman discloses the step of (f) determining a condition of the located portion (figure 6).

In regards to claim 49, Balas in view of Hochman discloses the condition comprises a member selected from the group consisting of normal squamous tissue, metaplasia, CIN I, CIN II, CIN III, and CIN II/III (para. 21).

In regards to claim 50, Balas in view of Hochman discloses determining a condition of the located portion based at least in part on evolution of mean intensity of the located portion (col. 3 line 50- col. 4 line 10).

In regards to claim 51, Balas in view of Hochman discloses obtaining a biopsy specimen within the located portion prior to determining the condition of the located portion (col. 1 lines 50-67).

In regards to claim 52, Balas in view of Hochman discloses the characteristic of interest is a suspicion of pathology (para. 2).

In regards to claim 53, Balas in view of Hochman discloses the tissue comprises cervical tissue (para. 20).

In regards to claim 54, Balas in view of Hochman discloses the tissue comprises at least one member selected from the group consisting of epithelial tissue, colorectal tissue, skin, and uterine tissue (para. 20).

In regards to claim 55, Balas in view of Hochman discloses the step of illuminating the tissue using a white light source, a UV light source, or both (para. 21).

In regards to claim 56, Balas discloses steps a) accessing a temporal sequence of images of the tissue following application of the chemical agent to the tissue (paragraph 20).

Balas does not expressly disclose step b) determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent, step c) repeating step (b), thereby differentiating regions according to how tissue in each region responds to the chemical agent.

However, Hochman discloses step b) determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent (col. 6 lines 5-20), step c) repeating step (b), thereby differentiating regions according to how tissue in each region responds to the chemical agent (col. 6 lines 20-30).

Balas & Hochman are combinable because they are from the same field of endeavor i.e. biomedical imaging (paragraph 2, Balas) & (col. 1 line 20-34, Hochman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Hochman into the system of Balas.

The suggestion/motivation for doing so would have been to one of ordinary skill in the art to combine because it allows a method of improving detections of tumors quickly for patients by reducing the amount of the time the patients spends the in hospital (col. 2), as taught by Hochman.

Therefore, it would have been obvious to combine Balas with Hochman to obtain the invention as specified in claim 56.

In regards to claim 59, Balas in view of Hochman discloses repeating step (b) for each of a plurality of pairs of selected regions (col. 7 lines 39-50).

In regards to claim 60, Balas in view of Hochman discloses the measure of similarity indicates a similarity in evolution of mean intensity of each region following application of the chemical agent (col. 2 line 62-col. 3 line 10).

In regards to claim 62, Balas in view of Hochman discloses a member selected from the group consisting of acetic acid, formic acid, propionic acid, butyric acid, Lugol's iodine, Shiller's iodine, methylene blue, toluidine blue, and indigo carmine (para. 21).

In regards to claim 63, Balas in view of Hochman discloses the chemical agent comprises acetic acid (para. 21).

In regards to claim 64, Balas in view of Hochman discloses the step (d) locating a portion of the tissue with a characteristic of interest, the located portion corresponding to at least one of the differentiated regions (col. 5 line 40-65 & col. 7 line 39-50).

In regards to claim 65, Balas in view of Hochman discloses the step e) determining a condition of the located portion (Figure 6).

In regards to claim 65, Balas in view of Hochman discloses the condition comprises a member selected from the group consisting of normal squamous tissue, metaplasia, C1N I, CIN II, CIN III, and CIN II/III (para. 21).

In regards to claim 67, Balas in view of Hochman discloses step (e) comprises determining a condition of the located portion based at least in part on evolution of mean intensity of the located portion (col. 3 line 50- col. 4 line 10).

In regards to claim 68, Balas in view of Hochman discloses the tissue comprises cervical tissue (para. 20).

In regards to claim 69, Balas in view of Hochman discloses the tissue comprises at least one member selected from the group consisting of epithelial tissue, colorectal tissue, skin, and uterine tissue (para. 20).

In regards to claim 70, Balas discloses a light source that illuminates a tissue (para. 20), a camera that obtains a temporal sequence of images of the tissue following application of the chemical agent to the tissue (paragraph 20).

Balas does not expressly disclose step i) based on at least in part on the temporal sequence of images, determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent, step ii) repeating step (i), thereby

differentiating regions according to how tissue in each region responds to the chemical agent.

However, Hochman discloses i) based on at least in part on the temporal sequence of images (col. 5 lines 55-65), determining a measure of similarity between two selected regions of the tissue, the measure of similarity indicating how similarly tissue in each region responds to the chemical agent (col. 6 lines 5-20), step ii) repeating step (i), thereby differentiating regions according to how tissue in each region responds to the chemical agent (col. 6 lines 20-30).

Balas & Hochman are combinable because they are from the same field of endeavor i.e. biomedical imaging (paragraph 2, Balas) & (col. 1 line 20-34, Hochman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Hochman into the system of Balas.

The suggestion/motivation for doing so would have been to one of ordinary skill in the art to combine because it allows a method of improving detections of tumors quickly for patients by reducing the amount of the time the patients spends the in hospital (col. 2), as taught by Hochman.

Therefore, it would have been obvious to combine Balas with Hochman to obtain the invention as specified in claim 70.

5. Claims 41, 42, 57 & 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman (USPN 6,671,540) and Balas (US Publication 2002/0007123) in further view of Thirion et al (USPN 6,373,998).

With regards to claim 41, Balas (as modified by Hochman) discloses all of the claimed subject matter as already set forth above in paragraph and incorporated herein by reference.

Balas (as modified by Hochman) does not expressly disclose step (c) further comprises merging the two selected regions into a single region if the measure of similarity satisfies a predetermined criterion.

However, Thirion discloses step (c) further comprises merging the two selected regions into a single region if the measure of similarity satisfies a predetermined criterion (Figure 6 item 20).

Balas (as modified by Hochman) & Thirion are combinable because they are from the same field of endeavor i.e. bio medical imaging (paragraph 2, Balas) & (col. 1 line 20-34, Hochman) & (col. 1 lines 10-25, Thirion)

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Thirion into the system of Balas (as modified by Hochman).

The suggestion/motivation for doing so would have been to one of ordinary skill in the art to combine because the improved system determines a more accurate measure of change to the 3-D images over a change in the time, and improves the

method of how system determines contract in the changing images (col. 1 line 65- col. 2 line 24).

Therefore, it would have been obvious to combine Thirion with Balas (as modified by Hochman) to obtain the invention as specified in claim 41.

In regards to claim 42, Balas and Hochman in further view of Thirion discloses steps (c) and (d) together comprise iteratively segmenting an area of the tissue into regions according to evolution of mean intensity of each region following application of the chemical agent (paragraph 23 & 24).

With regards to claim 57, Balas (as modified by Hochman) discloses all of the claimed subject matter as already set forth above in paragraph and incorporated herein by reference.

Balas (as modified by Hochman) does not expressly disclose step (c) further comprises merging the two selected regions into a single region if the measure of similarity satisfies a predetermined criterion.

However, Thirion discloses step (c) further comprises merging the two selected regions into a single region if the measure of similarity satisfies a predetermined criterion (Figure 6 item 20).

Balas (as modified by Hochman) & Thirion are combinable because they are from the same field of endeavor i.e. bio medical imaging (paragraph 2, Balas) & (col. 1 line 20-34, Hochman) & (col. 1 lines 10-25, Thirion)

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Thirion into the system of Balas (as modified by Hochman).

The suggestion/motivation for doing so would have been to one of ordinary skill in the art to combine because the improved system determines a more accurate measure of change to the 3-D images over a change in the time, and improves the method of how system determines contract in the changing images (col. 1 line 65- col. 2 line 24).

Therefore, it would have been obvious to combine Thirion with Balas (as modified by Hochman) to obtain the invention as specified in claim 57.

In regards to claim 58, Balas and Hochman in further view of Thirion discloses steps (b) and (c) together comprise iteratively segmenting an area of the tissue into regions according to evolution of mean intensity of each region following application of the chemical agent (paragraph 23 & 24).

6. Claim 45, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman (USPN 6,671,540) and Balas (US Publication 2002/0007123) in further view of Butler et al (USPN 5,267,179).

With regards to claim 45, Balas (as modified by Hochman) discloses all of the claimed subject matter as already set forth above in paragraph and incorporated herein by reference.

Balas (as modified by Hochman) does not expressly disclose step (c) comprises computing an N-dimensional dot product of mean signal intensities of the two selected regions.

However, Butler discloses step (c) comprises computing an N-dimensional dot product of mean signal intensities of the two selected regions (col. 2 lines 48-52).

Balas (as modified by Hochman) & Butler are combinable because they are from the same field of endeavor i.e. optical image processing (col. 1 lines 10-15, Butler) & (paragraph 21, Balas) & (col. 3 lines 50-65, Hochman) .

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Butler into the system of Balas (as modified by Hochman).

The suggestion/motivation for doing so would have been obvious to one of ordinary skill in the art to because the device will be able to perform the necessary correlations at great speed without the need for many components (col. 1 line 67-col. 2 line 2), as taught by Butler.

Therefore, it would have been obvious to combine Balas (as modified by Hochman) with Butler to obtain the invention as specified in claim 45.

With regards to claim 61, Balas (as modified by Hochman) discloses all of the claimed subject matter as already set forth above in paragraph and incorporated herein by reference.

Balas (as modified by Hochman) does not expressly disclose step (b) comprises computing an N-dimensional dot product of mean signal intensities of the two selected regions.

However, Butler discloses step (b) comprises computing an N-dimensional dot product of mean signal intensities of the two selected regions (col. 2 lines 48-52).

Balas (as modified by Hochman) & Butler are combinable because they are from the same field of endeavor i.e. optical image processing (col. 1 lines 10-15, Butler) & (paragraph 21, Balas) & (col. 3 lines 50-65, Hochman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine and incorporate the teachings taught by Butler into the system of Balas (as modified by Hochman).

The suggestion/motivation for doing so would have been obvious to one of ordinary skill in the art to because the device will be able to perform the necessary correlations at great speed without the need for many components (col. 1 line 67-col. 2 line 2), as taught by Butler.

Therefore, it would have been obvious to combine Balas (as modified by Hochman) with Butler to obtain the invention as specified in claim 61.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to O'Neal R. Mistry whose telephone number is (571) 272-4052. The examiner can normally be reached on 9am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M. Mehta can be reached on (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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